Quality-Significant Procurement Guideline - 2.9.G (02/26/04)

Note: This is an Interim Policy awaiting DOE/NNSA approval.

Last Update: (02/26/04) RShibata:kma - 2.9.G.0

This revision clarifies the role of the SCR in processing Quality-Significant (Q-Sig) Procurements.

Definitions

10 CFR 830 Subpart A – the prevailing federal regulation regarding quality processes in a nuclear environment. The two criteria that pertain to procurement processes are Criterion 7 and 8, as follows: Criterion 7 -Performance/Procurement (1) Procure items and services that meet established requirements and perform as specified; (2) Evaluate and select prospective suppliers on the basis of specified criteria; and (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services; and Criterion 8 – Performance/Inspection and Acceptance Testing. (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

Dedication - process whereby an item is evaluated by the Requester to determine if pre-established critical characteristics are met and the item(s) can be accepted for a specific quality-significant application.

Price-Anderson – Congress enacted the Price-Anderson Act in 1957 as an amendment to the

Atomic Energy Act of 1954 to encourage the development of the nuclear industry and to ensure prompt and equitable compensation in the event of a nuclear accident. Subsequently, the Price-Anderson Amendments Act (PAAA) of 1988 made three significant changes: 1) greatly increased the amount of indemnification; 2) made indemnification mandatory in all DOE contracts; and 3) established a system of civil penalties for DOE indemnified contractors, subcontractors, and suppliers.

Procurement Quality Assurance Representative (PQAR) – person who has the responsibility for managing the quality-significant infrastructure within Procurement. This individual is the subject matter expert for issues and requests for assistance regarding quality-significant procurements.

Quality Assurance Representative - a person who is a member of the Quality Assurance Working Group (QAWG) having been selected by the Division Vice President to represent the Division on matters affecting quality and to participate in the implementation of the Corporate Quality Assurance Program.

Quality-Significant – relating to the procurement of goods and services where quality aspects are of greater importance due to their potential to harm people, property, and the environment.

Goods and services are quality-significant if their use will:

- Cause a significant adverse impact to program/project cost, schedule, or performance if it fails; or
- Significantly impact the safe operation of any SNL facility or activity;
- Involve the use, handling, or storage of radioactive material or radiation-generating devices, or involve exposure to ionizing radiation;
- Relate to the design, analysis, manufacture, or assembly of hardware, equipment, or software for present or future use with radioactive material; or
- Be used in any safety-significant or safety-critical system, component, or application whose failure could adversely affect people, property, or the environment.

Exceptions:

1. Quality-Significant procurements for staff augmentation personnel may be exempt from quality-significant procedures as determined appropriate by the Requester. Requester should assess the risk involved in the contracted position and determine whether their internal procedures adequately manage that risk. Specifics of the job to be considered when evaluating risk include: the critical nature of the work, level of supervision, degree of decision-making discretion, inherent hazards, training, education and experience requirements, etc.
2. Quality-significant procurements may not apply to activities involving only incidental use (nonscheduled, non-routine usage, occasional use) and generation of radioactive material or radiation such as check and calibration sources, use of radiation sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.
3. This corporate process requirement does not apply to internal transfers of items when Reapplication, Org. 10267-1, is not involved. If an item is obtained from Reapplication, it shall not be used in a quality-significant application. For an internal transfer of critical/hazardous items, the Sandian taking possession should follow the requirements of CPR400.1.1 – ES&H Manual, understand how it had previously been used and obtain any necessary pedigree documentation to ensure the transferred item will meet the needs of the receiving organization.

Quality-Significant Database – electronic on-line database of quality-significant information pertaining to evaluated suppliers and dedicated purchases: https://www-irn.sandia.gov/cgi-bin/sqa/sqa.cgi?submit_button=SQADatabaseQuery

Supplier Quality Evaluation - any documentation or supplier quality assessment that gives assurance that the supplier has the capability of producing or manufacturing the goods or providing the service and that the goods/services to be procured will function as intended. Once performed, an evaluation is performed, an evaluation is effective for up to 36 months depending on the Requester's confidence.

Background - 2.9.G.1

This guidance is the mechanism by which the Procurement Center will comply with CPR001.3.2, "Corporate Quality Assurance Program" and DOE quality assurance requirements. Compliance with this guidance satisfies the contractual requirement for compliance with DOE O 414.1A and the legal requirement for compliance with 10 CFR 830.120.

Responsibilities of the SCR - 2.9.G.2

The Requester is responsible for the initial determination of quality-significant applicability.

- If the Requester determines the procurement is quality-significant, appropriate actions shall be taken by involved persons to comply with the Q-Sig Handbook.
- If the Requester determines that the procurement is not quality-significant and the assigned buyer agrees, the action will be placed without regard to Q-Sig procedures. If the buyer does not agree, the involved parties shall review and discuss the procurement specification and statement of work until agreement is reached (this may require a management decision). Should the involved managers not agree on Q-Sig applicability, it will be reviewed and determined by M. Lynn Jones, Vice President, Integrated Enabling Services, delegated this responsibility by Joan Woodard on June 17, 2003.

The SCR must fulfill an integral role in the process. The SCR is responsible for:

- becoming familiar with purchase requirements that may require a quality-significant procurement,
- reviewing Requester documentation to verify that an inspection plan has been written,
- working with the Requester to ensure Supplier Evaluation/Dedication is performed, and
- after receipt and inspection, if necessary, communicating any deficiencies to the Contractor and negotiating a resolution.

Therefore, the SCR must be knowledgeable about the ***Quality-Significant Procurement Handbook*** in order to assist the Requester in the process either through direct support of the

customer or to refer them to the proper subject matter expert or ***job aid.***

Analyzing the Purchase Requisition for Consideration of Quality-Significant Issues - 2.9.G.3

For any procurement the SCR should review the Purchase Requisition for consideration of quality-significant issues. One of four Purchase Requisition situations listed below will occur. The SCR must review the particulars of the requirement and gain a complete understanding of the user's needs before proceeding.

Situation	Action
A Quality-Significant (Q-Sig) Purchase Requisition is sent to a Q-Sig designated SCR.	Proceed with acquisition using Q-Sig procedures.
A Purchase Requisition is not coded Q-Sig, is sent to a Q-Sig designated SCR, and appears to involve Q-Sig issues.	The SCR is to contact the Requester directly to verify whether they considered Q-Sig applicability (see note below). If the SCR needs further assistance regarding the Q-Sig Program, they should contact the Procurement Quality Assurance Representative (PQAR)
A Q-Sig Purchase Requisition is sent to a non-Q-Sig designated SCR.	Forward the Purchase Requisition to the appropriate Q-Sig designated buyer.
A Purchase Requisition is not coded Q-Sig, is sent to a non-Q-Sig designated buyer, and appears to involve Q-Sig issues, e.g., the statement of work appears to the SCR to involve a safety issue (i.e., if the item fails after being put into use, it would likely harm people, property, or the environment).	Forward the issue to the PQAR/Department Manager/Q-Sig designated SCR who will work with the Requester.

Note: The SCR shall document whether Q-Sig is applicable or not in Section I of the PAS/PAD.

Quality Significant Coding - 2.9.G.3.a

A requisition is properly coded as quality-significant (Oracle category) as follows:

- QUALITY SIGNIFICANT
- MFG

Processing a Quality-Significant Procurement - 2.9.G.4

The following steps are used in processing a Quality-Significant procurement.

Step	Who	Action
1	Requester	Determine the method of quality control. This must be one of two ways: Dedication (most often used) or Supplier Quality Evaluation. • Annotate the "Note to Buyer" field with either "Dedication" or Supplier Quality Evaluation". • If the Requester is performing a supplier quality evaluation, the Requester shall ensure that the findings are input into the Quality-Significant Database.
2	SCR	• Ensure that the item/service description is adequate to enable the Contractor to deliver the intended item/service. The Requester should be contacted if more information is required. • Check 'Note to Buyer' field to ensure that the Requester has included a reference to their inspection plan. If no reference is included, contact the Requester to get their assurance that an inspection plan will be created prior to delivery. The inspection plan is an internal document that will be used by the Requester to inspect/test upon receipt of the item or during/at completion of the service. Generally, it will not be included in the contract or sent to the Contractor. The SCR will incorporate appropriate clauses in Section I of the contract in accordance with the "Boilerplates and Q-Sig Clauses" Job Aid. • Include relevant information/determinations regarding Q-Sig applicability in the PAS/PAD. • For nuclear and radioactive material (see Guideline 6.15.G.1), contact the Radiation Generating Device and Radioactive Source Registrar for approval with the following information (This individual as of 1-1-2004 is Kevin Rolfe, Organization 3123.) o isotope o quantity of material o requester name and organization • The Radiation Generating Device and Radioactive Source Registrar will

		approve or disapprove of the purchase and coordinate with other Sandia organizations as required.
3	Requester	• Upon receipt, the Requester will inspect/test in accordance with their inspection plan. For goods/services that fail inspection, the Requester should use the "Return of Deviating/Warranted Material Report", SF-6891-S. The SCR should resolve non-compliance with the Requester and Supplier. • The Requester shall complete a QUEST evaluation for each Q-Sig Purchase Order.

Applicable Clauses - 2.9.G.5

- 106-REV (for UCC-based boilerplates)
- 107-PAA (for Nuc/Rad appl)
- 108-QAP
- 109-QSP

Send feedback on ideas and information on this page to the Process Expert, Randy Shibata.


Randy Shibata


Karen Archibeque